REMARKS

A. Amendment to Title

The title of the application is amended to better correspond with the claims and avoid confusion with prior patents or applications of common priority.

B. Terminal Disclaimer

Without admission that the present claims are obvious in view of the claims of the cited patents of assignee, and to expedite allowance of the present application, a terminal disclaimer is submitted herewith with respect to all patents cited as a basis for double patenting rejection in pages 4 – 9 of the Office Action.

Applicants note that claim 12 was rejected solely on the basis of double patenting. Claim 12 is amended to be in independent format including all limitations of the base claim as filed. Therefore, claim 12 is submitted as allowable.

C. Consistency with Prior Claims Allowed Over the Cited Art

M.P.E.P. Section 706.04 states, in pertinent part, "Full faith and credit should be given to the search and action of a previous examiner unless there is a clear error in the previous action or knowledge of other prior art. In general, an examiner should not take an entirely new approach or attempt to reorient the point of view of a previous examiner, or make a new search in the mere hope of finding something."

The claims of the present application are similar (but not identical) to those found in various ones of the issued patents cited by the Examiner as a basis for an obvious-type double patenting rejection. For example, claims 1 – 5 are similar to claims 1 – 5 of U.S. Pat. No. 6,250,307. For comparison, claim 1 of the '307 patent is set forth in the following table in side-by-side relation to claim 1 of the present application.

U.S. 6,250,307 Claim 1	Present Application Claim 1 (as amended herein)
A method for treating snoring of a patient, said method comprising:	A method for treating an airway condition of a patient where said airway condition is characterized by a dynamic response of a tissue of said airway to airflow, said method comprising:
selecting an implant dimensioned so as to be implanted into a soft palate of said patient,	selecting an implant dimensioned so as to be implanted into said tissue,
said implant having mechanical characteristics for said implant,	said implant having mechanical characteristics for said implant,
at least in combination with a fibrotic tissue response induced by said implant,	at least in combination with a fibrotic tissue response induced by said implant,
to alter a dynamic response of said soft palate of said patient to air flow past said soft palate without application of force external to said soft palate;	to passively alter said dynamic response of said tissue without application of force external to said tissue;
implanting said implant into said soft palate to alter said dynamic response	implanting said implant into said tissue to alter said dynamic response.

The Examiner will note that one difference of the claims is that the '307 patent is directed to the specific preferred embodiment of placing an implant in the "soft palate" while the present application is directed to placing an implant in "tissue of said airway". Such tissue can include the soft palate but can also include, for example, nasal, tongue and pharyngeal wall tissue.

In view of the broader scope of the claims of the present application, Applicants admit the scope of relevant prior art is greater than in the '307 patent. Therefore, Applicants admit that U.S. Pat. 5,979,456 ("Magovern") (pharyngeal wall treatment for obstructive sleep apnea) and U.S. Pat. No. 6,106,541 ("Hurbis") (nasal stent for nasal dilation) are relevant prior art for the present application even though they would not be analogous for purpose of the claims of the '307 patent. Therefore, this amendment seeks to clarify the present claims in view of those references.

However, as to other prior art (notably, U.S. Pat. No. 5,176,618 ("Freedman")), Applicants note that similar claim language of the '307 patent was deemed allowable over Freedman for reasons that distinguish the present claims over Freedman. Enclosed is the Notice of Allowability in Ser. No. 09/398,991 (now the '307 patent) with paragraph 3 of the Notice specifically allowing the claim language over the magnet embodiment of Freedman. Nevertheless, to expedite allowance, further amendments are made to clarify the novel structure with respect to Freedman.

D. Declaration of Paul J. Buscemi, Ph.D.

In support of this amendment, a declaration is submitted by Paul J. Buscemi, Ph.D. Dr. Buscemi has a doctorate in biomaterials and has many years of experience in research and development in biomaterials with a heavy emphasis in studying and evaluating tissue response (including fibrosis) to implanted materials. Throughout these Remarks, reference is made to various portions of the Buscemi Declaration.

E. Discussion of Cited References

1. Rejections Based on Freedman (U.S. Pat. No. 5,176,618)

Freedman was cited to reject claims 1 – 5 and 7 – 10. The dependent claims depend from either claim 1 or 5. While Applicants believe amendment to claims 1 and 5 is not necessary to distinguish over Freedman in view of M.P.E.P. Sec. 706.04 (cited above), for the purpose of expediting allowance, amendments are made to these independent claims to more clearly distinguish Freedman.

a. Required Use of Magnetic Force

In all of claims 1 – 5 and 7 – 10, the implant is recited as acting to stiffen tissue without application of external force. As noted in the allowance of the '307 patent, this distinguishes over Freedman. Moreover, independent claims 1, 5 and 6 are amended to recite the implant is placed in a target tissue and stiffening occurs by reason of the material stiffness and fibrosis and without application of force external to the target tissue. For example, in Freedman, if the target tissue is the soft palate, there is a force by reason of a magnet external to the target tissue (e.g., a non-implanted magnet or a magnet in other tissue such as the tongue).

In Freedman, cooperating magnets (e.g., magnets 1 and 8 in Fig. 1 of Freedman) are used to space the soft palate 3 from posterior pharyngeal wall 7. The magnets 1, 8 are positioned with magnetic poles (N,S) aligned for the magnet 8 beneath the chin 66 to draw a magnet 1 in the soft

palate 3 away from the posterior pharyngeal wall 7. In the embodiment of Fig. 5, magnets 14, 15 are imbedded in the patient and positioned with magnetic poles to position the palatal magnet 10 to urge the soft palate 3 away from the posterior pharyngeal wall 7. Therefore, in all embodiments of Freedman, a magnetic force is created which requires at least two magnets, one of which is in the tissue to be treated, the other is in opposing tissue.

b. Implants of Freedman Are Rigid and Not Flexible

Claims 5 – 10 recite the implant is flexible. Freedman does not teach a flexible implant.

The magnets 1, 10 of Freedman are rigid (described in Freedman, Col. 6, lines 40 – 44 as samarium cobalt and neodymium iron). Therefore, Freedman does not contemplate an implant which flexes with the tissue in which the magnet is embedded. (Buscemi Declaration, ¶ 7.c.).

Freedman does not show or suggest any implant having mechanical characteristics to stiffen or dampen a target tissue. The Freedman device only acts on the target tissue in response to a force from a second magnet external to the target tissue. (Buscemi Declaration, ¶ 7.a and 7.b.). The Freedman device does not and cannot flex along an axis as the target tissue bends and does not add stiffening to the target tissue.

c. Freedman Avoids And Teaches Away From A Fibrotic Response

In all of claims 1 – 5 and 7 – 10, the fibrotic response of the implant contributes to stiffening of the tissue. Freedman teaches away from tissue stiffening with a fibrosis-inducing implant. (Buscemi Declaration, ¶ 7.d.). All of claims 1 – 5 and 7 – 10 now recite the implant is formed of a material selected to induce a fibrotic response of material amount. While "material amount" is a relative term, one of ordinary skill in the art would recognize and understand what is claimed, in light of the specification. Namely, *di minimus* fibrosis which does not contribute to the tissue resistance is not material. (Buscemi Declaration, ¶ 5.d.). Such relative term is clearly permitted in the claim. M.P.E.P. Section 2173.05(b).

All claims reflect that mechanical characteristics of a permanent implant abate snoring by altering dynamic response. These characteristics include natural stiffness or dampening of the implant as well as stiffening fibrotic response induced by the material of the implant. For example, page 7, lines 25 – 28 describe polyester material to induce a fibrotic response to stiffen to the soft palate. The claims further receipt that the implant alters dynamic response without application of external force (thus clearly distinguishing from Freedman).

Freedman does not suggest a device of material to induce a fibrotic response. Quite the opposite, Freedman coats the magnet with a smooth polymer coating (such as urethane or silicone as used in heart pacemaker implants. (Freedman col. 7, lines 4 – 9). One of ordinary skill in the art recognizes this as attempting to avoid (rather than induce) a fibrotic response.

2. German Patent DE 44 12 190 A1 ("Schreiber")

Schreiber was cited to reject claims 1 – 5 and 7 – 10. The dependent claims depend from either claim 1 or 5. Since a flowable medium (such as the injected collagen of Schreiber) has little mechanical strength to impart to tissue, Applicants do not believe Schreiber anticipates these claims. Nevertheless, to expedite allowance, Applicants amends each of independent claims 1 and 5 to recite the implant is a solid of pre-formed dimensions.

The text of Schneider (including claims) clearly indicates Schneider is referring to injection of flowable, injectable collagen and not a solid of preformed dimensions. Specifically, in addition to repeatedly stating the substance is "injected" (by itself indicating a flowable substance), Schneider states the collagen "is injected successively and beginning with small doses while observing the change of the voice" (emphasis added). (Buscemi Declaration, ¶ 8.b.).

The present invention pertains to a solid implant. The implant is clearly identified as a solid implant having pre-formed dimensions (i.e., not a flowable substance).

It would not be obvious to modify Schneider to be a solid. Schneider is clearly concerned with avoiding vocal effects from over-stiffening the palate. Therefore, Schneider begins injection of the flowable substance in small doses. Vocal effects are observed. If there are no adverse vocal effects, a second dose is administered and the process is repeated.

Therefore, Schneider teaches away from a solid pre-formed implant since Schneider wants to control the process with progressive doses. As a result it would not be obvious to alter Schneider to a solid implant since such an alteration deprives Schneider of the dose control deemed essential by Schneider.

Schneider is more similar to sclerosing therapy treatments of the soft palate. In these procedures, a fluid, flowable sclerosing agent is injected into the soft palate to create a scar. Such a treatment is described in LaFrentz et al., "Palatal Stiffening Techniques for Snoring in a novel Canine Model", Abstracts of the Twenty-Second Annual MidWinter Meeting of the Association for Research in Otolaryngology, Abstract No. 499, Vol. 22, pp. 125 – 126 (February

13 – 18, 1999) (cited in Applicants Information Disclosure Statement submitted with the filing of the present application).

3. U.S. Pat. No. 5,979,456 ("Magovern")

Magovern was cited to reject claims 1 – 7, 9 and 11. Of these claims 1, 5 and 6 are independent. These claims are amended to more clearly distinguish over Magovern to expedite allowance even though Applicants believe that, as filed, Magovern does not anticipate the claims. These amendments include reciting the implant is a passive implant acting without application of external energy. Further, relevant amendments include identifying the material of the implant inducing a fibrotic response of material amount.

a. Magovern Requires Activation By An Energy Source to Alter Physiology

The Examiner has directed Applicants' attention to the embodiments of Figs. 8 – 10 and implant 80a, 80b, 90a, 90b and 101 – 104 with the Examiner asserting the implants have a greater longitudinal than transverse dimension and that the implants are flexible.

Applicants' agree with the Examiner's observation on page 3 of the Office Action that implants of Magovern are effective to open an airway "[w]hen activated". (Office Action, p. 3, fourth to last line, emphasis added). The Examiner recognizes that Magovern is an active implant which only functions when activated. This activation is heating or cooling to alter the crystalline structure of the material of Magovern. (Buscemi Declaration, ¶ 5.b.).

Independent claims 1, 5 and 6 are amended to clearly recite the alteration of tissue response is passive and does not require an activation force.

b. Magovern Does Not Teach A Material Which Imparts A Fibrotic Sufficient When Combined With Passive Mechanical Stiffness to Alter Physiology

i. There is No Evidence Supporting a Conclusion that Fibrosis is Inherent

Applicants' do not agree with the Examiner's statement on page 3, second to last sentence, that "the implants inherently cause at least some fibrotic tissue response" (emphasis added). This statement of inherency is made without supporting facts or technical reasoning as required by M.P.E.P. Section 2114 IV which states "'In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of

the applied prior art.'" Quoting *Ex parte Levy,* 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (Emphasis original). Further, one of ordinary skill in the art would recognize that any fibrosis is *di minimus* and would not be in an amount sufficient to alter tissue response or materially stiffen tissue. (Buscemi Declaration, ¶ 5.c and 5.d).

ii. Even Magovern Were to Have Some Stiffness, It would Be Inadequate to Materially Alter Tissue Stiffness

Moreover, Applicants note the present claims do not recite "at least some fibrotic tissue response". Instead, the claims recite the fibrotic response sufficient in combination with the passive mechanical characteristics (e.g., stiffness) of the implant to alter tissue response to airflow. In Magovern, the implanted device only affects physiology when activated by an energy source (as already noted by the Examiner). Neither the passive material qualities, any fibrotic response, nor any combination of mechanical stiffness and fibrosis is adequate in Magovern to alter tissue stiffness. (Buscemi Declaration, ¶ 5.c and 5.d).

The implants of Magovern are described as one or more suture-like threads of shape-memory material inserted into musculature. (Magovern, col. 7, lines 56 – 59). The shape-memory material is described in column 5, lines 48 – 56. Suture-like threads of such material in musculature do not have a significant fibrotic response. Furthermore, such materials are highly compliant such that the material strength and any miniscule fibrotic response would not alter tissue response to airflow. (Buscemi Declaration, ¶ 5.c and 5.d).

4. U.S. Pat. No. 6,106,541 ("Hurbis")

Hurbis was cited to reject claims 1 – 7, 9 and 11. Of these claims 1, 5 and 6 are independent. These claims are amended to more clearly distinguish over Hurbis to expedite allowance even though Applicants believe that, as filed, Hurbis does not anticipate the claims. Particularly, amendments to claims include reciting the implant as being formed of a material selected to induce fibrosis of a material amount.

Hurbis intentionally selects a material for avoiding a fibrotic response. The structure of the Hubris nasal dilator 10 is shown in Fig. 4 in cross-section and includes an internal skeleton structure 24and an external encasing sheath 26. The encasing sheath 26 "must consist of a material that is biocompatible when implanted into the face. Suitable materials include expanded polytetrafluroethylene [sic] (PTFE) materials ...". (Hubris, col. 3, line 65 through col. 4, line 1). Hubris lauds the safe historical use of such material in implants for the face. (Hubris, col. 4, lines

1 – 11). Those skilled in the art will recognize that expanded polytetrafluoroethylene is very low fibrosis-inducing material. (Buscemi Declaration, ¶ 6.c). Hurbis teaches away from a material selected to induce fibrosis.

Moreover, Hurbis would want to avoid fibrosis to avoid adverse cosmetic effects. The implant of Hurbis is just beneath the skin and overlying cartilage or bone. Fibrosis would result in bulking which would have an adverse cosmetic appearance on the nose. (Buscemi Declaration, ¶ 6.a).

F. Supplemental Information Disclosure Statement

Submitted herewith is a supplemental Information Disclosure Statement citing the Ersek article which was cited in a related application. It is believed the teachings of Ersek are no more material than those already considered by the Examiner.

G. Conclusion

Applicants submit this application is now in condition for allowance. Reconsideration and Notice of Allowance are solicited. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,

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